K102964

GRIFOLS

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MAR - 7 2011

510(k) Summary

1. **Date 510(k) Summary Prepared:** 4 March 2011

2. **510(k) Owner:** Grifols USA, LLC

3. **Submitter:** Grifols USA, LLC

Submitter Name: Grifols USA, LLC.
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4. **Device Information**

Proprietary and Established Names: Eu-tTG® IgA & Eu-tTG® IgG
Common Names: Human Tissue Transglutaminase IgA & IgG

5. **Regulatory Information:**

Regulation No.: 21 CFR § 866.5660
Regulation Section: Multiple autoantibodies immunological test system
Classification: Class II
Product Code: MVM, Autoantibodies, Endomysial (Tissue Transglutaminase)
Panel: Immunology (82)

6. **Predicate Devices:**
Eu-tTG® IgA umana (K010625), predicate for Eu-tTG® IgA
Aeskulisa tTG G (K042644), predicate for Eu-tTG® IgG

7. Device Description

Each test kit for Eu-tTG® IgA & Eu-tTG® IgG consists of one (1) microtiter plate (12 strips with 8 microwells coated with the human recombinant tTG antigen), assay controls (positive and negative), a ready-to-use set of five (5) calibrators, Horseradish Peroxidase (HRP) goat anti-human IgA or IgG conjugate, serum diluent, Tetramethylbenzidine (TMB) enzyme substrate, stop solution, and washing solution required for the assay.

8. Intended Use

The Eu-tTG® IgA is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgA specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

The Eu-tTG® IgG is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgG specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

9. Summary of Comparison with Predicate Device

The proposed devices (Eu-tTG® IgA & Eu-tTG® IgG) have been compared with their predicate devices (Eu-tTG® IgA umana, K010625 & Aeskulisa tTG G, K042644, respectively), and found to be substantially equivalent.

The design, features, technological characteristics, specifications and performance of the proposed devices have been compared with those of the predicate devices, as shown in Tables 1, 2, 3 and 4.

Table 1 Device Similarity Between Eu-tTG® IgA and Predicate (Eu-tTG® IgA umana, K010625)

SIMILARITIES		
	Device	**Predicate**
Item	Eu-tTG® IgA	Eu-tTG® IgA umana (K010625)
Intended Use	The Eu-tTG® IgA is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgA specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	Eu-tTG® IgA Umana Assay is a qualitative ELISA test for the *in vitro* diagnostic detection of IgA antibody against the recombinant enzyme tissue transglutaminase (tTG) in human serum. This test is designed for use as an aid in the diagnosis of Celiac Disease.
Methodology	ELISA	Same
Analyte	Anti-human tissue transglutaminase (tTG) IgA antibodies	Same
Capture Antigen	Human recombinant tTG	Same
Detection Antibody	Goat anti-human IgA conjugate	Same
Enzyme Conjugate	Horseradish peroxidase (HRP)	Same
Substrate/Chromogen	TMB	Same
OD Reading	450 nm on spectrophotometer	Same
Positive Control	Human serum positive for tTG IgA Antibodies	Same
Negative Control	Human serum	Same
Controls	One positive control One negative control	Same
Storage	2-8° C	Same
Sample Volume Required	100 µL	Same
Sample Diluent	Ready-to-use	Same
Wash Solution/Buffer	20 X concentrated	Same

Table 2 Device Differences Between Eu-tTG® IgA and Predicate (Eu-tTG® IgA umana K010625)

DIFFERENCES		
	Device	**Predicate**
Item	Eu-tTG® IgA	Eu-tTG® IgA Umana Assay (K010625)
Assay Format	Semi-quantitative	Qualitative
Cutoff	9 AU/mL	7 AU/mL (Ages 2 to Adult); 5 AU/mL (Children < 2 years)
Calibrators	Set of 5, Values in AU/mL: Calibrator S1: 0 Calibrator S2: 10 Calibrator S3: 20 Calibrator S4: 50 Calibrator S5: 100	One calibrator: 16 AU/mL
Incubation Times	45-30-15 minutes	60-30-30 minutes
Screening Dilution	1:101	1:26
Linear Range	4.2-99.9 AU/mL	NA
Limit of Detection	1.6 AU/mL	NA

Table 3 Device Similarity Between Eu-tTG® IgG and Predicate (Aeskulisa tTG G, K042644)

SIMILARITIES		
	Device	**Predicate**
Item	Eu-tTG® IgG	Aeskulisa tTG G (K042644)
Intended Use	The Eu-tTG® IgG is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgG specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.	The AESKULISA tTG G is a solid phase enzyme immunoassay for the semi-quantitative and qualitative detection of IgG antibodies against tissue transglutaminase (tTG) in human serum. The assay is an aid in the diagnosis of celiac disease (gluten-sensitive enteropathy) and should be used in conjunction with other serological tests and clinical findings. For *in vitro* diagnostic use only.
Methodology	ELISA	Same
Analyte	Anti-human tissue transglutaminase (tTG) IgG antibodies	Same
Capture Antigen	Human recombinant tTG	Same
Detection Antibody	Goat anti-human IgG conjugate	Same
Enzyme Conjugate	Horseradish peroxidase (HRP)	Same
Substrate/Chromogen	TMB	Same
Screening Dilution	1:101	Same
OD Reading	450 nm on spectrophotometer	Same
Positive Control	Human serum positive for tTG IgG Antibodies	Same
Negative Control	Human serum	Same
Storage	2-8° C	Same
Sample Volume Required	100 µL	Same

Table 4 Device Differences Between Eu-tTG® IgG and Predicate (Aeskulisa tTG G, K042644)

DIFFERENCES		
	Device	**Predicate**
Item	Eu-tTG® IgG	Aeskulisa tTG G (K042644)
Assay Format	Semi-quantitative	Qualitative or Semi-quantitative
Cutoff	20 AU/mL	15 U/mL
Calibrators	Set of 5, Values in AU/mL: Calibrator S1: 2 Calibrator S2: 10 Calibrator S3: 20 Calibrator S4: 50 Calibrator S5: 100	Set of 6, Values in U/mL Calibrator F: 0 Calibrator E: 3 Calibrator D: 10 Calibrator C: 30 Calibrator B: 100 Calibrator A: 300
Incubation Times	45-30-15 minutes	Protocol A: 30-15-15 minutes Protocol B: 30-30-30 minutes
Controls	One positive control One negative control	One positive control One negative control One cut-off control

DIFFERENCES		
	Device	**Predicate**
Linear Range	4.1-99.8 AU/mL	1-100 U/mL
Limit of Detection	1.5 AU/mL	1.0 U/mL
Sample Diluent	Ready-to-use	5x concentrated
Wash Solution/Buffer	20x concentrated	50x concentrated

10. Standard/Guidance Document Referenced

The following standards were referenced in the submission:

- CLSI EP5-A2, "Evaluation of Precision Performance of Quantitative Measurement Methods"
- CLSI EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach"
- CLSI EP7-A2, "Interference Testing in Clinical Chemistry"
- CLSI EP17-A, "Protocols for Determination of Limits of Detection and Limits of Quantitation"
- CLSI C28-A2, "How to Define and Determine Reference Intervals in the Clinical Laboratory"
- CLSI EP9-A2, "Method Comparison and Bias Estimation Using Patient Samples"

11. Performance Characteristics

11.1 Analytical Performance

11.1.1 Precision Study

The intra-run precision studies were each performed in one (1) assay run. Results are summarized in Tables 5 and 6.

Table 5 Intra-run Precision Results for Eu-tTG® IgA

Sample No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Mean (AU/mL)	86.4	59.4	38.5	37.6	28.0	13.2	6.6	4.2	2.9	2.5
SD	3.8	4.0	1.3	0.8	1.2	1.1	0.3	0.2	0.1	0.1
CV%	4.4	6.7	3.3	2.1	4.4	8.6	3.9	3.7	2.6	4.0

Table 6 Intra-run Precision Results for Eu-tTG® IgG

Sample No.	1	2	3	4	5	6	7	8	9	10
Mean (AU/mL)	87.0	63.9	58.5	53.8	42.9	39.9	39.8	33.1	9.9	8.9
SD	3.32	2.96	5.07	4.37	3.14	2.28	3.61	2.95	0.27	0.56
CV%	3.8	4.6	8.7	8.1	7.3	5.7	9.1	8.9	2.7	6.3

The inter-run (between days) precision study results are summarized in Table 7 and 8.

Table 7 Inter-run Precision Results for Eu-tTG® IgA

Sample No.	1	2	3	4	5	6	7	8	9	10
Mean (AU/mL)	85.1	59.9	38.2	32.6	28.2	11.4	7.1	4.0	2.7	2.7
SD	2.70	2.3	0.9	3.0	2.0	0.6	0.7	0.4	0.3	0.2
CV%	3.2	3.8	2.4	9.2	7.2	5.6	10.2	10.2	9.7	8.0

Table 8 Inter-run Precision Results for Eu-tTG® IgG

Sample No.	1	2	3	4	5	6	7	8	9	10
Mean (AU/mL)	89.5	68.4	52.5	45.2	39.8	37.1	36.2	36.2	9.6	8.3
SD	3.03	4.74	1.82	3.24	1.60	3.07	1.85	2.24	0.44	0.66
CV%	3.4	6.9	3.5	7.2	4.0	8.3	5.1	6.2	4.6	7.9

The inter-lot precision study results are summarized in Table 9 and 10.

Table 9 Inter-lot Precision Results for Eu-tTG® IgA

Serum Sample No.	1	2	3	4	5	6	7
Mean (AU/mL)	92.2	68.5	62.0	26.1	15.1	4.5	2.5
S.D.	5.6	2.0	6.6	1.3	0.2	0.3	0.1
C.V. (%)	6.1	2.9	10.6	5.0	1.0	5.6	5.4

Table 10 Inter-lot Precision Results for Eu-tTG® IgG

Serum Sample No.	1	2	3	4	5	6	7
Mean (AU/mL)	89.4	67.0	42.3	19.3	17.6	14.6	10.3
S.D.	3.75	4.73	0.88	0.78	0.27	1.55	0.68
C.V. (%)	4.2	7.1	2.1	4.0	1.5	10.6	6.6

11.1.2 Linearity/Assay Reportable Range

Linearity was studied using three (3) positive serum samples each for the Eu-tTG® IgA and Eu-tTG® IgG. Each sample was diluted with a low concentration serum sample at around the limit of detection (LoD), 1.6 AU/mL for Eu-tTG® IgA and 1.5 AU/mL for

Eu-tTG® IgG, respectively, using a dilution scheme. The results of one (1) representative sample for Eu-tTG® IgA show a slope of 0.968 (95% C.I. 0.899 – 1.037), Y-intercept of -1.616 (95% C.I. -5.763 – 2.531) and R^2 of 0.9925. The results of one (1) representative sample for Eu-tTG® IgG show a slope of 0.917 (95% C.I. 0.860 – 0.974), Y-intercept of -1.407 (95% C.I. -4.831 – 2.016) and R^2 of 0.9933.

The results of the study support a linear range of 4.1-99.8 AU/mL for Eu-tTG® IgA, and 4.2-99.9 AU/mL for Eu-tTG® IgG. The claimed assay range is 1.6 (LoD) to 100 AU/mL for Eu-tTG® IgA, and 1.5 (LoD) to 100 AU/mL for Eu-tTG® IgG.

11.1.3 Traceability, Stability and Expected Values (Controls and Calibrators)

- **Traceability**

  Calibrators are not traceable to any recognized standards. Calibrators are dilutions of the pooled serum of tTG antibody from patients with Celiac disease. The new calibrator and control lots are formulated from an array of tTG antibody positive sera obtained from various commercial plasma centers stored at -70°C. The calibrators and controls are taken from different pooled sera. As new lots of calibrators are developed, studies are performed to calibrate values against original calibrators. Each lot of calibrator is also tested in comparison with normal human sera, clinical samples and internal standards. The concentration values of the calibrators are as follows:

Calibrator	IgA Assay Value	IgG Assay Value
Cal S5	100 AU/mL	100 AU/mL
Cal S4	50 AU/mL	50 AU/mL
Cal S3	20 AU/mL	20 AU/mL
Cal S2	10 AU/mL	10 AU/mL
Cal S1	0 AU/mL	2 AU/mL

- **Stability**

  Stability studies support the expiration date claims of 12 months at 2-8°C for both Eu-tTG® IgA and Eu-tTG® IgG.

- **Sample Stability**
  Specimens should be stored at 2-8°C for no longer than five (5) days. For longer storage, serum specimens should be frozen at -20°C. Repeated freezing and thawing of samples should be avoided.

11.1.4 Detection Limit

The limits of blank (LoB) and the limits of detection (LoD) were calculated for both Eu-tTG® IgA and Eu-tTG® IgG, as shown in Table 11.

Table 11 Limits of Blank and Limits of Detection for Eu-tTG® IgA and Eu-tTG® IgG

	LoB (AU/mL)	LoD (AU/mL)
Eu-tTG® IgA	0.05	1.6
Eu-tTG® IgG	0.02	1.5

11.1.5 Analytical Specificity and Interference

A cross reactivity study was performed for both Eu-tTG® IgA and Eu-tTG® IgG using 73 characterized clinical patient samples from individuals with autoimmune disorders, such as: Hashimoto's Thyroiditis, Graves' Disease, Antinuclear Antibodies/Systemic Lupus Erythematosus (ANA/SLE) positive and Cyclic Citrullinated Peptide (CCP) positive; patients with IBD and *H. pylori* infection. One (1) CCP positive, two (2) Hashimoto's Thyroiditis and one (1) Graves' Disease out of 73 samples (4/73, 5.5%) were tested positive for Eu-tTG® IgA. One (1) Hashimoto's Thyroiditis and two (2) Graves' Disease out of 73 samples were tested positive with the Eu-tTG® IgG (3/73, 4.1%).

Interference was studied by mixing the serum samples with known tTG antibody levels with potentially interfering substances. The study results demonstrated that hemoglobin (up to 2 g/L), bilirubin (up to 342 µmol/L), rheumatoid factor (up to 100 AU/mL) or lipids (triglycerides up to 130 mg/dL) does not significantly interfere with the performance of the Eu-tTG® IgA and Eu-tTG® IgG.

11.1.6 Assay Cut-off

The normal range of the assay was established by testing 153 samples, of which 103 are healthy subjects and 50 non-celiac controls (IBD patients), on each assay.

The assay cut-off values for Eu-tTG® IgA was determined as follows:

<9 AU/mL	Negative
9-16 AU/mL	Borderline
>16 AU/mL	Positive

The assay cut-off value for Eu-tTG® IgG was determined as follows:

<20 AU/mL	Negative
≥20 AU/mL	Positive

11.2 Method Comparison Studies

11.2.1 Eu-tTG® IgA

A method comparison study was performed which compared the Eu-tTG® IgA to a comparator test using 179 clinical samples. These samples consist of clinically diagnosed celiac positive (clinical history and/or biopsy) and negative samples. The negative samples were obtained from healthy blood donors, IBD patients, patients affected by food intolerances and patients with autoimmune or infectious diseases. All samples were tested using Eu-tTG® IgA and the comparator test kit. The results of the studies are summarized in Tables 12 and 13.

Table 12 Results of Method Comparison Study (Eu-tTG® IgA with Borderline Samples Considered Positive Using Cut-off of 9 AU/mL)

		Eu-tTG® IgA umana Test (K010625) (Cut-off = 7 AU/mL)		
		Positive	**Negative**	**Total**
Eu-tTG® IgA	**Positive**	70	2	72
	Negative	4	103	107
	Total	74	105	179

Positive % Agreement = 94.6% (95% CI 86.7% - 98.5%)
Negative % Agreement = 98.1% (95% CI 93.3% - 99.8%)
Overall % Agreement = 96.6% (95% CI 92.8% - 98.8%)

Table 13 Results of Method Comparison Study (Eu-tTG® IgA with Borderline Samples Considered Negative Using Cut-off of 16 AU/mL)

		Eu-tTG® IgA umana Test (K010625) (Cut-off = 7 AU/mL)		
		Positive	**Negative**	**Total**
Eu-tTG® IgA	**Positive**	61	0	61
	Negative	13	105	118
	Total	74	105	179

Positive % Agreement = 82.4% (95% CI 71.8% - 90.3%)
Negative % Agreement = 100.0% (95% CI 96.5% - 100.0%)
Overall % Agreement = 92.7% (95% CI 87.9% - 96.1%)

11.2.2 Eu-tTG® IgG

A method comparison study was performed which compared the Eu-tTG® IgG to a comparator test using 178 clinical samples. These samples consist of 51 clinically diagnosed Celiac positive (clinical history and/or biopsy), which include 8 total IgA deficient celiac patients, and 127 negative samples. The negative samples were obtained from healthy blood donors, IBD patients, patients affected by food intolerances and patients with autoimmune or infectious diseases. All samples were tested using Eu-tTG® IgG and the comparator test kit. The results of the studies are summarized in Table 14.

Table 14 Results of Method Comparison Study

		Aeskulisa tTG G (K042644) (Cut-off = 15 AU/mL)		
		Positive	**Negative**	**Total**
Eu-tTG® IgG (Cut-off = 20 AU/mL)	**Positive**	48	7	55
	Negative	6	117	123
	Total	54	124	178

Positive % Agreement = 88.9% (95% CI 77.4% - 95.8%)
Negative % Agreement = 94.4% (95% CI 88.7% - 97.7%)
Overall % Agreement = 92.7% (95% CI 87.8% - 96.1%)

11.3 Clinical Studies

11.3.1 Eu-tTG® IgA

For the Eu-tTG® IgA assay, the clinical study included 363 clinical samples, of which 121 are positive celiac patients and 242 are negative samples from healthy subjects and patients with autoimmune disorders, infectious disease and IBD. The positive celiac patient samples were diagnosed with clinical findings and/or confirmed with biopsy. Tables 15 and 16 demonstrate the clinical performance of the Eu-tTG® IgA assay.

Table 15 Clinical Performance Results for Eu-tTG® IgA (Borderline Samples Considered Positive Using Cut-off of 9 AU/mL)

		Celiac Disease		
		Positive	**Negative**	**Total**
Eu-tTG® IgA	**Positive**	118	4	122
	Negative	3	238	241
	Total	121	242	363

Sensitivity = 97.5% (95% C.I. 92.9% - 99.5%)
Specificity = 98.3% (95% C.I. 95.8% - 99.5%)
Positive Predicative Value (PPV) = 96.7% (95% C.I. 91.8% - 99.1%)
Negative Predicative Value (NPV) = 98.8% (95% C.I. 96.4% - 99.7%)

Table 16 Clinical Performance Results for Eu-tTG® IgA (Borderline Samples Considered Negative Using Cut-off of 16 AU/mL)

		Celiac Disease		
		Positive	**Negative**	**Total**
Eu-tTG® IgA	**Positive**	103	2	105
	Negative	18	240	258
	Total	121	242	363

Sensitivity = 85.1% (95% C.I. 77.5% - 90.9%)
Specificity = 99.2% (95% C.I. 97.0% - 99.9%)
PPV = 98.1% (95% C.I. 93.3% - 99.8%)
NPV = 93.0% (95% C.I. 89.2% - 95.8%)

11.3.2 Eu-tTG® IgG

For the Eu-tTG® IgG assay, the clinical study included 407 clinical samples, of which 165 are positive celiac patients, and 242 are

negative samples from healthy subjects, and patients with autoimmune disorders, infectious disease and IBD. The positive celiac patient samples were diagnosed with clinical findings and/or confirmed with biopsy. Table 17 demonstrates the clinical performance of the Eu-tTG® IgG assay.

Table 17 Clinical Performance Results for Eu-tTG® IgG

		Celiac Disease		
		Positive	**Negative**	**Total**
Eu-tTG® IgG	**Positive**	94	14	108
	Negative	71	228	299
	Total	165	242	407

Sensitivity = 57% (95% C.I. 49% - 64.6%)
Specificity = 94.2% (95% C.I. 90.5% - 96.8%)
PPV = 87.0% (95% C.I. 79.2% - 92.7%)
NPV = 76.3% (95% C.I. 71.0% - 81.0%)

11.4 Expected Values

The expected value in the normal population is negative. However, the incidence of celiac disease in the normal population is about 1%, some apparently healthy, asymptomatic individuals may test positive for the tTG antibodies.

12 Conclusion

The submitted material in this 510(k) Premarket Notification is sufficient to support a substantial equivalence decision with the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Grifols USA, LLC
c/o Ms. Catherine L. Wong
Director, Regulatory Affairs
2410 Lillyvale Avenue
Los Angeles, California 90032

MAR 07 2011

Re: k102964

Trade/Device Name:	Eu-tTG® IgA Eu-tTG® IgG
Regulation Number:	21 CFR§866.5660
Regulation Name:	Multiple autoantibodies immunological test system
Regulatory Class:	Class II
Product Code:	MVM
Dated:	February 7, 2011
Received:	February 8, 2011

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4.2 Indication for Use Statement for Eu-tTG® IgG

510(k) Number (if known): K102964

Device Name: Eu-tTG® IgG

Indication for Use:

The Eu-tTG® IgG is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgG specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102964

4.1 Indication for Use Statement for Eu-tTG® IgA

510(k) Number (if known): K102964

Device Name: Eu-tTG® IgA

Indication for Use:

The Eu-tTG® IgA is an *in vitro* diagnostic enzyme immunoassay for the semi-quantitative detection of IgA specific antibodies directed against tissue transglutaminase (tTG) in human serum. It is an aid in the diagnosis of celiac disease and should be used in conjunction with other serological tests and clinical findings.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k102964